GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1916
ANSWERED ON:07.03.2000
DUMPING OF DRUGS
K. MURALEEDHARAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether multinationals are dumping new drugs in India;

(b) if so, the details thereof and the reasons therefor;

(c) whether guidelines have been chalked out by the Government to ensure the quality and reasonable prices of these drugs; and

(d) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (INDEPENDENT CHARGE) (SH SHANMUGAM)
(a) No, Sir.

(b) Before any new drug is approved for marketing in the country, its safety and efficacy are invariably required to be established through clinical trials in the Indian Population, published data and quality control parameters tested by the Central Drugs Laboratory to ensure that the new drugs conforms to the prescribed quality control testing, as per the Drugs & Cosmetics Rules, 1945.Another criterion for approval of any new drug is that the said drug is approved by the regulatory authorities of the country of origin nor banned in any other country.

(c)&(d) Government has laid down guidelines for fixing of drug prices in
(i) the Drug Policy, 1986 (as modified upto September, 1994) and
(ii) the Drugs (Prices Control) Order, 1995 (DPCO)IN fixing the prices under DPCO, 1995, the objectives of the Drug Policy, 1986 modified in September, 1994, as well as the price determination formula in DPCO, 1995, are kept in view.As per the Government Policy, the National Pharmaceutical Pricing Authority (NPPA), does not ordinarily fix the prices of drug/formulation that do not fall under Schedule-I of DPCO, 1995. These are monitored and corrective action taken wherever called for.